Application No. 10/526,285

Amendment dated March 2, 2006

Response to Office Action dated December 2, 2005

This listing of claims will replace all prior versions, and listing, of claims in the application.

**Listing of Claims:** 

1. (Currently Amended) A pharmaceutical composition comprising metaxalone

and at least one pharmaceutically acceptable excipient[s], characterized in that the

pharmaceutical composition has enhanced oral bioavailability as compared to the conventional

pharmaceutical composition of metaxalone available commercially when administered without

food to a patient who has fasted.

2. (Currently Amended) A pharmaceutical composition as claimed in claim 1,

wherein the metaxalone used is in a pharmaceutically acceptable solubility-improved form.

3. (Original) A pharmaceutical composition as claimed in claim 2, wherein the

solubility-improved form is micronised metaxalone.

4. (Original) A pharmaceutical composition as claimed in claim 2, wherein the

solubility-improved form is a salt form of metaxalone.

5. (Currently Amended) A pharmaceutical composition as claimed in claim 2,

wherein the solubility-improved form is a high-energy crystalline form of metaxalone.

6. (Original) A pharmaceutical composition as claimed in claim 2, wherein the

solubility-improved form is amorphous metaxalone.

7. (Original) A pharmaceutical composition as claimed in claim 1, wherein the

composition comprises a mixture of metaxalone and a solubilizing agent.

8. (Currently Amended) A pharmaceutical composition as claimed in claim 1

comprising metaxalone and pharmaceutically acceptable excipients, wherein the metaxalone

used has comprises the following particle size distribution characteristics: 99% undersize value

between 10 and 40 µm, 90% undersize value between 6 and 30 µm, and 50% undersize value

between 3 and 10 m in diameter, characterised in that the pharmaceutical composition has

enhanced oral bioavailability.

2

Application No. 10/526,285 Amendment dated March 2, 2006

Response to Office Action dated December 2, 2005

9. (Currently Amended) A pharmaceutical composition as claimed in claim [8] 1,

wherein the metaxalone used has specific surface area per unit volume of more than 1.5m<sup>2</sup>/cm<sup>3</sup>.

10. (Currently Amended) A pharmaceutical composition as claimed in claim 9,

wherein the metaxalone used has specific surface area per unit volume of more than 2.5m<sup>2</sup>/cm<sup>3</sup>.

11. (Currently Amended) A pharmaceutical composition as claimed in claim 10,

wherein the metaxalone <del>used</del> has specific surface area per unit volume of more than 3.0m<sup>2</sup>/cm<sup>3</sup>.

12. (Currently Amended) A pharmaceutical composition as claimed in claim [8] 1,

wherein the metaxalone <del>used has</del> comprises the following particle size distribution

characteristics: 99% undersize value of 40μm, 90% undersize value of 30μm, and 50% undersize

value of 10µm.

13. (Currently Amended) A pharmaceutical composition as claimed in claim [12] 1,

wherein the metaxalone used has comprises the following particle size distribution

characteristics: 99% undersize value of  $30\mu m$ , 90% undersize value of  $14\mu m$ , and 50% undersize

value of  $6\mu m$ .

14. (Currently Amended) A pharmaceutical composition as claimed in claim [13] 1,

wherein the metaxalone used has comprises the following particle size distribution

characteristics: 99% undersize value of  $10\mu m$ , 90% undersize value of  $5\mu m$ , and 50% undersize

value of  $3\mu m$ .

15. (Currently Amended) A pharmaceutical composition as claimed in claim 1,

wherein the amount of metaxalone used is in the range of 400mg to 1600mg.

16. (Currently Amended) A pharmaceutical composition as claimed in claim 1,

wherein the pharmaceutically acceptable excipient includes comprises a wetting agent.

17. (Currently Amended) A pharmaceutical composition as claimed in claim 16,

wherein the wetting agent used is comprises a surfactant.

18. (Currently Amended) A pharmaceutical composition as claimed in claim 17.

wherein the surfactant used is comprises sodium lauryl sulfate.

3

Application No. 10/526,285 Amendment dated March 2, 2006 Response to Office Action dated December 2, 2005

19-22 (Cancelled)

23. (Previously Presented) A pharmaceutical composition as claimed in claim 1

wherein the pharmaceutical composition further comprises an analgesically effective amount of a

non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug

comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative,

biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts

thereof.

24. (Currently Amended) A pharmaceutical composition as claimed in claim [8] 2

wherein the pharmaceutical composition further comprises an analgesically effective amount of a

non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug

comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative,

biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts

thereof.

25-26 (Cancelled)

27. (New) A pharmaceutical composition comprising metaxalone and at least one

pharmaceutically acceptable excipient, wherein at least 99% of the metaxalone has a particle size

not more than about  $10\mu m$  in diameter.

28. (New) A pharmaceutical composition in solid dosage form comprising an

effective amount of metaxalone and at least one pharmaceutically acceptable excipient wherein

the dosage form has an enhanced oral bioavailability as compared to the metaxalone product of

New Drug Application No. 13-217.

4